DETAILED ACTION

Election

[01] Claims 18,20-23,35-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/1/11.

[02] Applicant assert that the MPEP "requires a comparison between the process as claimed (e.g., Applicants' claim 18) and the apparatus as claimed (Applicants' claim 1)." While this is undoubtedly the case, the MPEP permits restriction if "that the apparatus as claimed can be used to practice *another materially different process*." The MPEP does not require that the materially different process be *claimed*. Nor that the materially different process be disclosed. The MPEP only requires that a materially different process exist.

[03] In this case, the claimed method recites "receiving light *reflected from the body lumen wall* at the light detector." The claimed apparatus recites a light detector for "receiving reflected light." The claimed apparatus is broader in the sense that the reflected light need not be "reflected by the body lumen" as required by claim 18.

[04] Moreover, the recited reflection has greater weight in a method claim, since the captured light must have actually been reflected by a body lumen wall, whereas in the apparatus claim, the photodetector must only be *capable of* capturing light that has been reflected by a body lumen. Notably, photodetectors can not distinguish between direct and reflected light, nor between light reflected by body lumens and light reflected by other matter. In an apparatus claim, a light detector described as being functionally capable of capturing light reflected from a body lumen is not structurally different from a light detector generally. The capability of capturing light is inherent to the

term "light detector." The light detector in the method claim is used in a particular way – namely to receive light that is reflected from a body lumen – whereas the light detector in the apparatus claim is merely capable of capturing light. The latter claim lends itself to other methods, and is therefore properly restrictable.

[05] The Gilad publication (cited below as a §102(e) reference) illustrates the distinction set forth in MPEP §806.05(e). Gilad uses an optical sensor as a light detector for capturing light that is projected through or reflected by a gear that is responsive to capsule motion. To function properly, the generated light need not be reflected by a lumen wall. Accordingly, Gilad anticipates the apparatus of claim 1; does not anticipate the method of claim 18; and discloses a process for using that apparatus that is materially different from the method recited in claim 18.

Claim Objections

[06] Claim(s) 1,10 is/are objected to because of the following informalities. Appropriate correction is required.

[07] In claim 1, "level of light" should read "a level of light."

[08] In claim 10, "primary light source providing illumination source via the optical window" should read "primary light source providing illumination via the optical window."

Claim Rejections - 35 USC § 112, Paragraph One

[09] The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[10] Claim(s) 1,4-5,7-10,15-16,30-34 is/are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

[11] Claim 1 recites an illumination source and light detector positioned such that "a level of light emitted from the illumination source, reflected from the lumen walls, and incident on the light detector, is less when the lumen walls are relatively close to said outer shell." It is not clear how the structure of the device can ensure that more reflected light reaches the light detector independently of context. The device disclosed in the specification is just as capable of capturing *more* light when the lumen walls are relatively close to the outer shell. For example, the relatively-closer walls may be more reflective. Alternatively, they may be relatively closer, but not so close that the illumination source and light detector are not in the same light field. The disclosed invention is clearly capable, under certain circumstances, of capturing less light when the lumen walls are relatively close to the outer shell. But the language of the claim recites that the various elements are provided such that captured light *always* has a negative correlation with closeness of lumen walls. It is maintained that the disclosure does not enable such an arrangement.

[11a] Note: there is no enablement issue with a *processor* that makes such a correlation. A skilled artisan could easily make and use a processor that makes a determination of wall closeness based on capture of a certain level of light.

Claim Rejections - 35 U.S.C. 112, Paragraph Two

[12] The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[13] Claim(s) 8-10,34 is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[14] Claim 8 recites "a primary light source" and "a dedicated light source" in addition to the already-recited "illumination source." It is clear from the specification that two light sources are being utilized, but the claim suggests that three are being utilized. Applicant should make clear whether the "primary" and "dedicated" light sources are being claimed *in addition to* the "illumination source", or whether the "illumination source" is being *further limited* to one that is "primary" or "dedicated" or "primary" and "dedicated." If claim 8 recites "a device further comprising a primary light source and an imager", then the rejection would be overcome.

[15] Claim 34 is identical to claim 30, except for a typographical error in which "illumination source" is included where "illumination" is intended.

Claim Rejections - 35 USC § 102

[16] The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a)

> shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

[17] Claims 1,4-5,7-10,15-16,30-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Gilad (2004/0204630).

[18] With regard to claim 1: Gilad discloses an in-vivo system comprising:

[18a] an autonomous in vivo device for traversing lumens having different diameters, said device comprising:

- an outer shell ("shell 450" [0032]);
- an illumination source ("illumination source 213" [0021] and/or "light unit 460" [0033]); and
- a light detector receiving reflected light ("imager 217" and/or "sensor 430" [0033]);

[18b] the illumination source and the light detector positioned relative to the outer shell such that a level of light emitted from the illumination source, reflected from the lumen walls, and incident on the light detector, is [capable of being] less when the lumen walls are relatively close to said outer shell; and

[18c] a processor to, based on light received at the detector, determine the movement of the in-vivo device from a lumen having a first diameter to a lumen having a second diameter ("Processor 330 may receive and evaluate the current, which may help determine or indicate the movement of in-vivo device 205, and translate the current into in-vivo device motion data, for example, distance traversed or other motion parameters" [0026]. The device calculates distance traversed thorughout the entire gastrointestinal tract, which

inherently includes esophagus, stomach, small intestine, large intestine, each having different diameters).

[19] With regard to claim 4: the first diameter is a relatively small diameter lumen and wherein the second diameter is a larger diameter (e.g., small intestine and large intestine).

[20] With regard to claim 5: in vivo device comprises an imager ("217").

[21] With regard to claim 7: said detector is selected from the group consisting of: a CMOS, a CCD and a photodiode.

[22] With regard to claim 8: the illumination source is a dedicated light source ("460"), the device comprising a primary light source ("213") and an imager ("217").

[23] With regard to claim 9: the primary light source ("213") illuminates a body lumen for imaging said body lumen with said imager and wherein the dedicated light source ("460") illuminates a body lumen for determining the movement of the in vivo device with said light detector.

[24] With regard to claim 10: Gilad further discloses an optical window ("214") wherein the primary light source ("213") and the imager ("217") are positioned behind the optical window, the imager imaging via the optical window and the primary light source providing illumination via the optical window, and the light detector ("430") receiving light not via the optical window.

[25] With regard to claim 15: Gilad further discloses a controller, wherein said controller is configured to receive signals from said detector and to trigger an event to occur within said in-vivo device. See [0047]:

> [0047] At block 630, if substantial motionless is detected, the functionality of the in-vivo device or a part of the functionality may be limited, for example, the in-vivo device imaging module may be suspended or discontinued. According to other embodiments a mode of action or operation of the in vivo device may be changed, for example, the rate of frame uptake may be

increased or lowered, the illumination may be changed, or other modes may be affected.

[26] With regard to claim 16: Gilad further discloses a transmitter ("212").

[27] With regard to claim 30: Gilad discloses an optical window, wherein the primary light source and the imager are positioned behind the optical window, the imager imaging via the optical window and the primary light source providing illumination via the optical window, and the light detector receiving light not via the optical window.

[28] With regard to claim 31: the in-vivo device is a swallowable in-vivo device traversing the gastrointestinal tract and wherein the lumens are organs of the gastrointestinal tract.

[29] With regard to claim 32: the light detector is placed at a location on said outer shell.

[30] With regard to claim 33: the primary light source illuminates a body lumen for imaging said body lumen with said imager and the dedicated light source illuminates a body lumen for determining the movement of the in vivo device with said light detector.

[31] With regard to claim 34: Gilad discloses an optical window, wherein the primary light source and the imager are positioned behind the optical window, the imager imaging via the optical window and the primary light source providing illumination ~~source~~ via the optical window, and the light detector receiving light not via the optical window.

Conclusion

[32] The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

[32a] Meron (2002/0109774), Montalbo (7,044,908) and Halla (7,399,274) disclose capsules with light sources and photodetectors located all around the capsule.

[32b] Mizumoto (4,278,077) discloses a capsule where the objective lens and the light source share a light field only when the capsule is in a large diameter lumen. See Figure 1.

[32c] Iddan (7,251,383) discloses a capsule with a secondary light source and photodetector wherein capsule location might be determined from an analysis of a sample located in the view field of the photodetector.

[32d] Chen (2005/0074151) discloses a capsule endoscope that uses an "anatomical identity" index for analyzing captured reflected light and determining a position of a capsule based on the captured reflected light. Chen generates a "GI atlas" containing reference to lumens of various diameters.

[33] Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R Smith whose telephone number is (571) 272 6087 and whose email address is philip.smith@uspto.gov. The examiner can normally be reached between 9:00am and 5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen, can be reached on (571) 272 4963. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Philip R Smith/
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